REMARKS

The enclosed is responsive to the Office Action mailed on January 6, 2009. A Request for Continued Examination accompanies this Amendment. At the time the Examiner mailed the Office Action claims 1-2 were pending. By way of the present response applicants have amended claim 1 in order to more particularly point out and distinctly claim the subject matter which applicants regard as the invention. No claims have been canceled. New claim 18 has been added. As such, claims 1-2 and 18 are now pending. Applicants respectfully request reconsideration of the present application.

Applicants reserve all rights with respect to the applicability of the doctrine of equivalents.

Drawing and Specification

Correction has been made to the drawing and specification filed on September 19, 2007. In particular, correction has been made to correct a transposition of GAM and GA. Additionally, correction has been made to the specification to reference the date and address for the deposit as requested by the Examiner. No new matter has been added.

As described in multiple places throughout the specification, applicants teach the use of a processed ginseng product with enhanced pharmacological effects due to a serial treatment including acid-treatment and subsequent bio-converting treatment such as lactic fermenting. See, for example, the Technical Field on page 1 of the specification filed on September 19, 2007:

> The present invention relates to novel use of processed ginseng extract and the saponin compounds isolated therefrom for preventing and treating brain stroke and brain diseases in human or mammal. More

particularly, the present invention relates to novel use of processed ginseng product with enhanced pharmacological effects due to serial treatment i.e., acid-treatment and subsequent bio-converting treatment such as lactic fermenting and intestinal-bacterial fermenting process.

See also, for example, the first full paragraph on page 4 of the specification filed on September 19, 2007:

> The inventors of the present invention have intensively carried out the scientific investigation concerning the chemical constituents and pharmacological effects of a ginseng, in particular a processing method of a ginseng and physiological activity of the processed ginseng. As a result of the investigation, the inventors have discovered that through the serial treatment of an acid treatment and a subsequent fermentation treatment of the ginseng extract with lactic-acid bacteria or intestinal-bacteria, the extract of the processed ginseng extract shows substantially enhanced pharmacological effects. In particular, the extract prevents or treats brain strokes.

This process is embodied in Example 4 taught on page 15 of the specification filed on September 19, 2007. As described in further detail in the first full paragraph on page 9 of the specification filed on September 19, 2007, the acid treatment transforms saponins into Rg_3, and fermentation with bacteria forms ginsenoside Rh_2. This result is quantified in Table 1 on page 18 of the specification filed on September 19, 2007. Upon close analysis of Table 1, it is clear that the specific sequence of acid-treatment and subsequent fermentation with bacteria is required to obtain the increased sapopin fraction % of ginsenoside Rg_3 and ginsenoside Rh_2. Preparation of Comparative Example 1 (CE 1) did not include acid-treatment or subsequent fermentation. Preparation of Comparative Example 2 (CE 2) included acid-treatment, but no subsequent fermentation. Preparation of Example 1 (E 1) included fermentation, but it was not preceded by an acid-treatment. Preparation of Example 4 (E 4) embodied the serial treatment of acid-treatment and subsequent fermentation. As a consequence, the sapopin fraction % of ginsenoside Rg_3 and ginsenoside Rh_2 was significantly increased only in Example 4.

Because the disclosure of the specification is directed toward the serial treatment embodied in Example 4, it is clear that Example 4 (GAM) should reflect the lowest Ischemic area value in Fig. 1. Applicants respectfully submit that the values of Ischemic area for ginseng extract GA (Example 3, which has been acid-treated but not fermented) and ginseng extract GAM (Example 4, which has been acid-treated and subsequently fermented with bacteria) were unintentionally transposed in Fig. 1 and the related description on page 20 of the specification filed on September 10, 2007 as well as in the original drawing and specification filed on October 8, 2004.

Appropriate correction has been made.

35 U.S.C. § 112, First Paragraph, Rejections

The Examiner has rejected claims 1-2 as not meeting the enablement requirement under 35 U.S.C. § 112, first paragraph, inquiring whether a deposit of *Bifidobacterium KK-1 and Bifidobacterium KK-2* has been made pursuant to 37 C.F.R. 1.802. Applicants have submitted herewith an attorney declaration and evidence of deposit in accordance with the Budapest Treaty.

Accordingly, applicants respectfully submit that claims 1-2 comply with the formalities of 35 U.S.C. § 112, first paragraph, and request the withdrawal of the rejections.

35 U.S.C. § 112, Second Paragraph, Rejections

The Examiner has rejected claims 1-2 as being indefinite under 35 U.S.C. § 112, second paragraph, stating it is unclear to which "organic extract" the phrase "subsequently drying the organic extract by lyophilization or spray drying wherein the

organic extract is subsequently used for preventing or treating a stroke" is referring to. Applicants have amended the above referenced phrase to correctly refer to the "subsequently drying the pharmacologically active fraction or sapopin compound."

The Examiner has additionally stated that the phrase "wherein the organic extract is subsequently used for preventing or treating a stroke" is indefinite. Applicants have removed the phrase from independent claim 1.

Accordingly, applicants respectfully submit that claims 1-2 comply with the formalities of 35 U.S.C. § 112, second paragraph, and request the withdrawal of the rejections.

35 U.S.C. § 103 Rejections

Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hashimoto* (T*, 03-277247) in view of *Lu* (N1, CN 1327850 A). In particular, the Examiner states on page 5 of the Office Action mailed January 6, 2009 "Please note that the art rejection below is made based on what Applicants are enabled for." Applicants respectfully submit that the combination does not teach each and every element of claims 1 and 2.

It is applicants' understanding *Hashimoto* discloses a method for producing a food ingredient by inoculating crushed, ground, or extracted ginseng with lactobacillus and fermenting it in order to improve the taste of the food ingredient. *Hashimoto* discloses that the main active ingredients are sapopins, including various kinds of ginsenosides. In particular, *Hashimoto* discloses that the ginseng product is to be used in traditional Chinese and Korean meals.

The ginseng is first crushed or ground as described in the detailed description of the process beinning on page 5 of the English translation provided by FLS, Inc. The ginseng may then be extracted with water or solvent. The only specific ginsenoside measured is ginsenoside Rg_1 as provided in Table 3 on page 15 of the English translation provided by FLS, Inc. The solvent is then eliminated and the extract is dried in order to bring the ginseng into a condition that allows the proliferation of lactobacillus. The dried ginseng extract is inoculated with a lactobacillus that is used in food products such as yogurt, cheese, Japanese pickels, and so forth. Specific examples of lactobacillus are provided in Table 1 in the middle of page 10 of the English translation provided by FLS, Inc. The inoculated ginseng is then fermented where acid is generated. Temperature is controlled to allow the lactobacillus to proliferate thereby improving the taste of the final product.

Applicants respectfully submit that *Hashimoto* does not disclose or suggest several important features of independent claim 1.

As a first matter, applicants respectfully point out that *Hashimoto* does not disclose or suggest "subsequently fermenting the organic extract with lactic-acid bacteria *Bifidobacterium KK-1 and Bifidobacterium KK-2"* as is taught and claimed by applicants in independent claim 1. Indeed, *Hashimoto* does not mention lactic acid bacteria *Bifidobacterium KK-1 and Bifidobacterium KK-2*, or suggest that fermenting with such would improve the taste of the final product.

Secondly, applicants respectfully submit that *Hashimoto* does not disclose or suggest extracting an organic extract from the gensing subsequent to "treating ginseng (*Panax ginseng or Panax quinquefolius*) with an acid solution selected from the group consisting of acetic acid, citric acid, lactic acid, and acid from acid-containing food" as is

taught and claimed by applicants in independent claim 1. The Examiner states on page 7 of the Office Action mailed January 6, 2009 that "extracting the ginseng with a solvent prior to mixing the ginseng with a source of acid, as taught by Hashimoto, rather than after, as claimed by Applicants, does not change the product." (emphasis by applicants). Applicants strongly disagree and respectfully refer the Examiner to Table 1 and the related text of the applicants' specification. As shown, the processed ginseng which is acid treated and subsequently fermented with *Bifidobacterium KK-1 and Bifidobacterium KK-1* in accordance with Example 4 results in a notable increase ginsenoside Rh2 and ginsenoside Rg3 which have a remarkable effect on treating and preventing brain stroke and brain diseases. This notable increase in ginsenoside Rh2 and ginsenoside Rg3 is unique to the method taught and claimed by applicants in independent claim 1. Accordingly, the final product obtained by the process disclosed in *Hashimoto* is different than the one obtained by the process taught and claimed by applicants in independent claim 1.

Furthermore, applicants respectfully draw the Examiner's attention to the recitation of MPEP § 2111.01(I) on page 7 of the Office Action mailed January 6, 2009. Applicants respectfully point out that MPEP § 2111.01(I) is related to the plain meaning interpretation of claims and does not support a contention that the order of steps in a method claim can be ignored.

With regard to *Lu*, it is applicants' understanding *Lu* discloses spray drying a ginseng saponin. Applicants respectfully submit that *Lu* does not remedy the deficiencies of *Hashimoto* as discussed above.

Accordingly, applicants respectfully submit that claims 1-2 are not obviated by *Hashimoto* in view of *Lu* under 35 U.S.C. § 103(a) and respectfully request the withdrawal of the rejection of the claims over the combination.

New Claim

New claim 18 requires "wherein said pharmacologically active fraction or saponin compound is selected from the group consisting of ginsenoside Rg3 and ginsenoside Rh2 and combination thereof." It is applicants' understanding new claim 18 is patentable for at least the reasons discussed above.

Conclusion

Applicants respectfully submit that the applicable rejections and objections have been overcome.

Pursuant to 37 C.F.R. 1.136(a)(3), applicant(s) hereby request and authorize the U.S. Patent and Trademark Office to (1) treat any concurrent or future reply that requires a petition for extension of time as incorporating a petition for extension of time for the appropriate length of time and (2) charge all required fees, including extension of time fees and fees under 37 C.F.R. 1.16 and 1.17, to Deposit Account No. 02-2666.

Respectfully submitted,

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